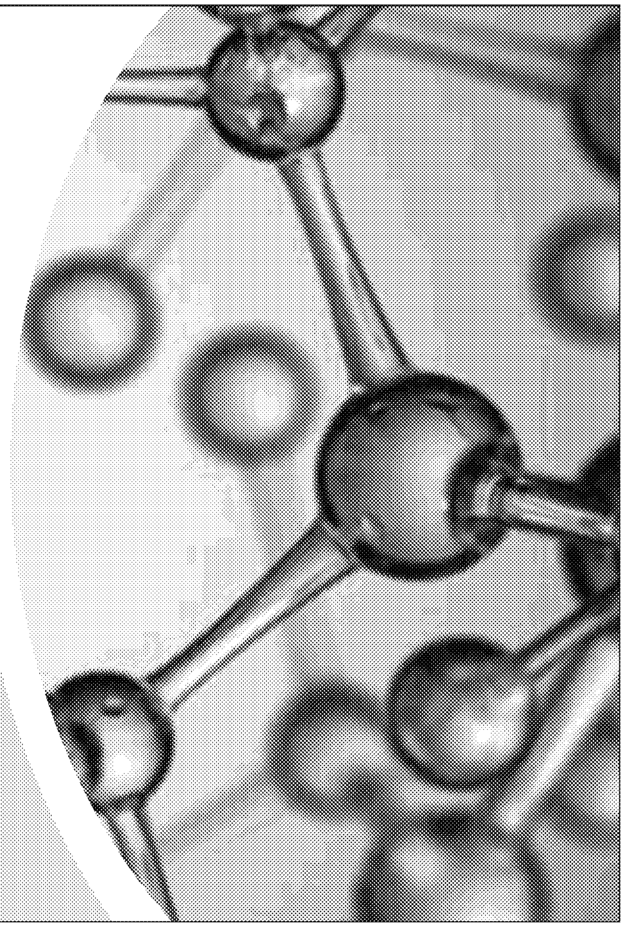
New PFAS Chemicals: Approaches and Path Forward



New Chemicals Division

February 22, 2021

Agenda

- Purpose of briefing
- PFAS statistics and working definition
- Risk assessment approaches
- Risk management approaches
- Pending/new PFAS notices and exemptions
- Previously granted PFAS exemptions
- Path forward and next steps

Purpose

- Following-up from the 2/10 PFAS briefing, this briefing will focus on the current science, challenges, statutory and regulatory options available, and path forward for managing PFAS chemicals under TSCA.

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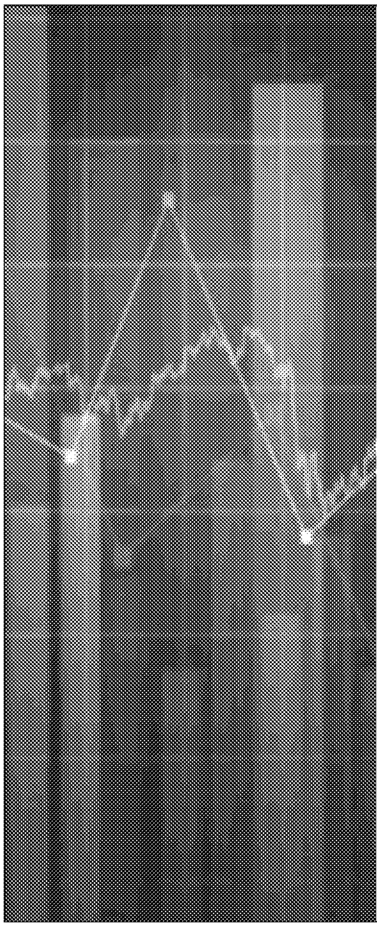
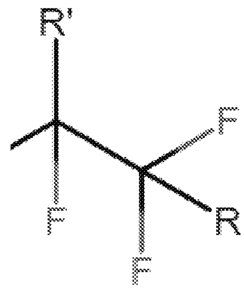


PFAS Statistics

- 1,344 PFAS currently on the TSCA Inventory (666 active)
  - This does not include environmental degradants, by-products, or impurities, per se
  - Substances on the Inventory are intended commercial products, but some of these substances can also be the degradants, by-products, and/or impurities of other Inventory-listed substances
- Approx. 700 Low Volume Exemptions granted
  - Not listed on the Inventory
- Currently, 30 new chemical PFAS notices undergoing EPA review:
  - 24 Premanufacture Notifications (PMNs)
  - 4 Low Volume Exemptions (LVEs)
  - 2 Significant New Use Notifications (SNUNs)

PFAS “Working” Definition

- Per- and polyfluoroalkyl substances (PFAS) is a broad category that includes perfluoro polymers, PFOA, PFOS, GenX and many other chemical substances
- There is no universally accepted definition, but there is an ongoing international effort (OECD and WHO) to create one.
  - OPPT definition is different than OECD
  - OPPT definition may have evolved over time, but the NDAA/TRI Listing and the 8(a)7 Rule are consistent and reflect this current definition
- OPPT applies the following “working” definition when identifying PFAS on the TSCA inventory.
  - Structure that contains the unit R-CF2-CF(R')(R'') where R, R', and R'' do not equal "H"
  - Carbon-carbon bond is saturated
  - Branching, heteroatoms, and cyclic structures are included



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Chemistry Assessment

- **Data Compiled**
  - Experimental physical-chemical property data for PFAS chemical (submitted and/or found in internal and external sources)
  - Analogues to submitted PFAS chemical (found in internal and external sources)
  - Manufacturing and processing methods
  - Uses (submitted and found in internal and external sources)
- **General Approach**
  - Review experimental physical-chemical property data submitted/available for new PFAS chemical
  - Review physical-chemical property data for analogues to new PFAS chemical
  - PFAS generally are not assessed using model-estimated physical-chemical properties
  - Conservative calls are given for physical-chemical property endpoints without available analogue information
- **Challenges**
  - PFAS have a wide variety of chemical properties

Risk Assessment Approach

- OPPT uses an integrated approach that draws on knowledge and experience across multiple scientific disciplines
- Risk-based evaluation that considers both hazard and exposure
- Lack of definitive scientific information about many chemicals in the PFAS family. OPPT uses confidential business information (CBI) and publicly available information for filling data gaps
- To conservatively assess the physical-chemical and environmental fate properties and the human health and environmental hazards of the various new PFAS chemicals, we evaluate:
  - Structurally similar analogues (read-across)
  - Expected environmental degradation products resulting from incomplete incineration, biodegradation and photolysis
  - Expected metabolites
  - Models are not typically used
- OPPT assesses exposure potential for workers, the general population and consumers depending on the uses of the new PFAS chemical
- Some PFAS risk assessments result in low risk based on the submitters' ability to limit release and worker exposure

Environmental Fate and Transport Assessment

- **General Approach**
  - Ex. 5 Deliberative Process (DP)
  - PFAS are not assessed with fate models (*e.g.*, EPISuite™)
  - Ex. 5 Deliberative Process (DP)
- **Changes in the Assessment Based on Evolving Science**
  - Data have been received via consent orders, MOUs, new chemical submissions and found in the existing chemical literature
  - Assessment of potential degradants resulting from biodegradation, incineration and photolysis.
  - Ex. 5 Deliberative Process (DP)
- **Testing and Challenges**
  - PFAS degradation testing commonly requires more analytical capability than for other chemicals
  - Some PFAS are more likely to have stable degradation intermediates than other new chemicals.
    - The stable degradation intermediates are commonly also PFAS
  - Ex. 5 Deliberative Process (DP)
  - PFAS like PFOA have been seen to have long half lives in mammals and bio-magnify in terrestrial and marine mammal food webs[1]. No standardized fate tests exist for chemicals with these types of behavior

1. Stockholm convention documents on PFOA

Environmental Hazard Assessment

- **General Approach**
  - Review chemical-specific test data (< 10% have environmental hazard test data)
  - Review analogue test data
  - PFAS are not assessed with modelling approaches (*e.g.*, QSARs)
    - Historically, predictive modeling was used to estimate environmental hazard endpoints in the absence of chemical-specific and analogue test data, but practice changed in the last 5-7 years
- **Challenges**
  - Lack of acute/chronic environmental test data
    - Few submissions have a full "base set" of acute/chronic environmental tests (including aqueous, terrestrial, and avian)
  - When data are submitted, it is usually acute environmental tests (up to 96 hours)
    - Much environmental test data on PFAS chemicals demonstrate chronic (and not acute) effects to the environment
- **Environmental Toxicity Testing**
  - Informed by pchem and fate properties
  - Acute test data (aqueous-only, sediment, terrestrial)
  - Chronic test data (aqueous-only, sediment, terrestrial, avian)

Human Health Hazard Assessment

- **General Approach**
  - Four structurally similar analogues are commonly used in the hazard/dose-response assessment of new PFAS (*i.e.*, PFOA, PFHxA, GenX, PFBS)--see Appendix for details
    - Read-across using PFOA/PFOS (less common; fewer long chain new PFAS)
    - PFHxA, PFBS, and GenX are common for C6s, C4s and ethers, respectively
- **Challenges**
  - Large uncertainties in the assessment
    - Limited set of analogues to evaluate human health hazards and risk: data extrapolation is conducted for a wide-variety of PFAS (*e.g.,* GenX is applied to all perfluoroether submissions)
    - Large differences in chemical retention among species: Humans eliminate PFAS much slower than laboratory species (PFHxA Half-lives: 768 hrs in humans vs 2-7 hrs in monkeys and rats); uncertainty factors based on C6
    - Degradation and metabolism are difficult to estimate with models: Critical for selecting appropriate analogue
    - When completed, the ongoing EPA assessments for 5 PFAS chemicals, including PFBS and PFHA will be adopted into NCD.
- **Human Health Toxicity Testing (since 2016)**
  - Based on information from PFOA, PFHxA and other tested perfluorinated compounds, EPA has often requested enhancements of reproductive/developmental toxicity protocols that include dosing and evaluation of offspring through sexual maturation
  - Pharmacokinetics data may be requested on multiple species to understand which species to use in toxicity testing

Exposure Assessment

- OPPT uses a life-cycle approach and modeling to estimate exposures (*i.e.*, ChemSTEER and E-FAST)
  - Model inputs are derived from submitter's information, EPA Generic Scenarios and Emission Scenario Documents relevant to the chemical's categories of use
- Exposures are calculated for human and ecological receptors
  - Workers (inhalation, dermal)
  - General population and eco, including susceptible populations (oral, inhalation)
    - Drinking water, fish ingestion and ecological exposures from water releases
    - Drinking water exposures from landfill release
    - Inhalation exposures in fence line communities from air and incineration releases
    - Consumer exposures are assessed if the submitter indicates an intended use
- Some submitters document low releases and worker exposures (*e.g.,* all wastes to hazardous waste incineration, closed systems)

Persistent, Bioaccumulative, and Toxic (PBT) Chemical Evaluation [1]

Ex. 5 Deliberative Process (DP)

Potential PFAS Testing

Chemistry

- Provide relevant physical chemistry data (MP, BP, VP, water solubility)
- Measure impurities and by-products

Fate

- Degradation testing appropriate to particular PFAS (photolysis/biodegradation)
- Testing of treatment efficiencies (e.g., wastewater treatment)
- Fish bioaccumulation testing with modification based on how PFAS accumulate in tissues
    - *In silico* and *in vitro* methods are not likely to be valid for many PFAS as they accumulate in tissues besides lipids

Hazard testing

- Environmental hazard – Acute and chronic toxicity tests including:
    - Aqueous-only (fish, aquatic invertebrates, and algae)
    - Sediment (aquatic invertebrates)
    - Terrestrial (invertebrates)
    - Avian (chronic-only)
- Human health hazard
    - Reproductive/developmental toxicity tests
    - Pharmacokinetics data

Risk Management Approach

- Risk management approach for PFAS new chemical notices has changed overtime
- Pre-Lautenberg, typical risk management included up-front testing or regulation via a consent order
  - Common terms of the consent order: triggered tiered testing, limit impurities, restrictions on disposal and releases to water, effluent monitoring, required worker protection, and hazard communication
- Initially after Lautenberg (2016/2017), risk determinations included "may present unreasonable risk" and "insufficient information." Consent orders with restrictions and testing were issued
- Ex. 5 Deliberative Process (DP)

Pending PFAS Notices and Exemptions

- 24 PMNs, 2 SNUNs and 4 LVEs pending
  - Ex. 4 CBI
  - The PMNs and SNUNs range from recent submissions to cases under suspension for "rework" for many years

***See appendix for further case details**

Deliberative Process / Ex. 5

Risk Management Options: for PMN

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PMN: Regulate via Section 5 Orders

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PMN: Regulate via TSCA Section 4 Test Rule

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TSCA Section 5(b)(4) Rule

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Risk Management Options: for LVEs

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LVE Revocations and Lessons Learned

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Path Forward and Next Steps

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22

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Appendix

Pending PFAS Exemptions

PFAS number	PFAS category	non-CBI or generic chemical name	non-CBI use or generic use	non-CBI Company name	non-CBI production volume	non-CBI consumer?
LVE1	PFC-R	Silane, trimethoxy (12, 12, 13, 13, 14, 14, 15, 15 ,15-nonafluoropentadecyl)-	Self-assembled monolayer for semiconductor manufacture.	Gelest	50	no consume
LVE2	R-PFC-R	CBI	Processing aid for chemical sysnthesis	CBI	CBI	no consume
LVE3	PFC	Perfluorinated cyclic hydrocarbon	Chemical tracer for production monitoring in oil and gas wells and for use in interwell tracing between injector and production oil and gas wells	Resman USA	CBI	oil and gas i
LVE4	PF ether poly	Alkene, halo-, modified, polymd., reduced, alkyl esters, reduced, alkoxylated, (isocyanato alkyl aryl) carbamates,	Polymer used in electronics manufacture	CBI	CBI	CBI

Pending PFAS PMNs

PFAS number	PFAS category	non-CBI or generic chemical name	non-CBI use or generic use	non-CBI Company name	non-CBI production volume	non-CBI consumer?
PMN1	PFC-R poly	Perfluoroalkylethyl methacrylate copolymer	Water and oil repellent	CBI	CBI	CBI
PMN2	PFC-R poly	Perfluoroalkylethyl methacrylate copolymer, sodium salt	Paper treatment	CBI	CBI	CBI
PMN3	PFC-R poly	Perfluoroacrylate polymer	CBI	CBI	CBI	CBI
PMN4	PFC-R poly	Perfluoroacrylate polymer	CBI	CBI	CBI	CBI
PMN5	PFC-R poly	Perfluoroalkylethyl methacrylate copolymer	Water and oil repellent	CBI	CBI	CBI
PMN6	PFC-R poly	Perfluoroalkylethyl methacrylate copolymer	Textile treatment	CBI	CBI	CBI
PMN7	PFC-R	Pentacyclo[9.5.1.13,9.15,15.17,13]octasiloxanealkylsubstituted, 3,5,7,9,11,13,15-heptakis(polyfluoroalkyl)-, acetate,	Additive to plastics	CBI	CBI	CBI
PMN8	PFC-R	Pentacyclo[9.5.1.13,9.15,15.17,13]octasiloxane, 1,3,5,7,9,11,13,15-octakis (polyfluoroalkyl)-	Additive to plastics	CBI	CBI	CBI
PMN9	PFC-R	Pentacyclo[9.5.1.13,9.15,15.17,13]octasiloxane, 1,3,5,7,9,11,13,15-octakis (polyfluoroalkyl)-	Additive to plastics	CBI	CBI	CBI
PMN10	PF ether	Perfluorodioxaalkanoyl fluoride	intermediate	CBI	CBI	CBI
PMN11	PF ether	Perfluoro-2-methy-trioxaalkanoyl fluoride	intermediate	CBI	CBI	CBI
PMN12	PF ether	Perfluorodioxaalkyl vinyl ether	intermediate	CBI	CBI	CBI
PMN13	R-PFC-R	perfluorodioxaalkyl vinyl ether	intermediate	CBI	CBI	CBI
PMN14	R-PFC-R	perfluorinated substituted 1,3-oxathiolane dioxide	intermediate	CBI	CBI	CBI
PMN15	R-PFC-R	perfluorinated vinyl haloalkane sulfonate salt	intermediate	CBI	CBI	CBI
PMN16	PF ether	perfluorinated vinyl haloalkane sulfonyl halide	intermediate	CBI	CBI	CBI
PMN17	R-PFC-R	Bis(triethoxysilylpropyl carbamate) perfluoropolyether	fluid resistant coatings	Luna Innovati	CBI	consumer
PMN18	H-PFC-R	sulfonium, carbocyclic-, salt with 1-(alkyl) 2-[4-[polyhydro-2-carbomonocyclic-5-(polyfluoro-2-sulfoalkyl)-4,7-methano-1,3-benzodioxol-2-yl]carbomonocyclic oxy]acetate (1:1)	photolithography	CBI	CBI	CBI
PMN19	H-PFC-R	alkenoic acid, polyhaloalkyl ester	monomer	CBI	CBI	CBI
PMN20	H-PFC-R	alkenoic acid, alkyl-substituted, polyhaloalkyl ester	monomer	CBI	CBI	CBI
PMN21	H-PFC-R	alkanoic acid, polyhalo-, halo-oxo-alkenyl-oxo-alkyl ester	monomer	CBI	CBI	CBI
PMN22	H-PFC-R	alkenoic acid, halo-substituted-polyhalo-alkyl ester	monomer	CBI	CBI	CBI
PMN23	H-PFC-R	alkanoic acid, polyhalo-(halo-oxo-alkenyl)oxyalkly ester	monomer	CBI	CBI	CBI
PMN24	H-PFC-R	alkenoic acid, halo-polylhaloalkyl ester	monomer	CBI	CBI	CBI
PMN25	R-PFC-R	Sulfonium, triphenyl-, polyfluoro-polyhydrospiro[9H-carbopolycyclic-9,2'-[4,7]methano[1,3]benzodioxole]-5'-alkenesulfonic acid (1:1),	photolithography	CBI	25 CBI	CBI

Pending PFAS SNUNs

PFAS number	PFAS category	non-CBI or generic chemical name	non-CBI use or generic use	non-CBI Company name	non-CBI production volume	non-CBI consumer?
SNUN1	PFC-R	polyfluroinated alkyl quaternary ammonium chloride	surfactant	CBI	CBI	CBI
SNUN2	PFC-R	1-Propanesulfonic acid, 2-methyl-2-[[1-oxo-3-[(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)thio]propyl]amino]-, sodium salt (1:1)	An anionic fluorosurfactant for main use (>98%) in firefighting foam concentrates such as AFFF (Aqueous Film Forming Foam) and AR-AFFF (Alcohol Resistant Aqueous Fim Forming Foam). An anionic fluorosurfactant for very minor use (<2%) in coatings and ink applications.	CBI	CBI	no

Table 4: Human Health Hazard/Dose-Response Assessment: Primary Analogues, PODs, and MOEs Used to Assess PFAS Chemicals

Chemical	Point of Departure (mg/kg-wb/day)	Benchmark Margin of Exposure (MOE)	Health Effect(s)	Notes	References
PFOA	0.0053	300	Developmental, immune	Used for C7 or higher PFAS chemicals	Health Effects Support Document for PFOA (EPA, 2016)
GenX	0.023	30	Liver	Used to assess all perfluoro ethers	Human Health Toxicity values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (EPA, 2018)
PFBS	4.2	30	Developmental toxicity	Narrowly applied to C3-4 sulfonic acids	Human Health Toxicity Values for PFBS (EPA, 2018)
PFHxA	10	23,000	Liver, Body weight	Large benchmark MOE is due to pharmacokinetic differences between experimental species	OECD 408 90-day oral study (CBI)

TABLE 1: TSCA INVENTORY PFAS NUMBERS

	CBI		Non-CBI			
Total	435		909		1344	
	Original Inventory (grandfathered)	PMN	Original Inventory (grandfathered)	PMN	Original Inventory (grandfathered)	PMN
Total	43	392	695	214	738	606
Active	1	254	289	122	290	376
Inactive	42	138	406	92	448	230

Table 2: PFAS Case Type by Inventory Flag/Regulatory Action				
	Active		Inactive	
	Original Inventory (grandfathered)	PMN	Original Inventory (grandfathered)	PMN
	x	88	x	2
5(e) Order + SNURs	x	65	x	3
	150	46	268	53

Table 3: PFAS by Carbon Chain Length

	Active	Inactive	Totals
>C8	97	211	308
C7/C8	105	122	227
C5/6	79	127	206
C4 or C3/C4	154	87	241
C2/3	73	29	102
Mixed	158	102	260
Totals	666	678	1344

- **Notes:**
- >C8: includes fluoropolymers and non-polymers with no range including 8 and below
- C7/8: this is because octanoic acid has 7 fluorinated carbons and octanesulfonic acid has 8 fluorinated carbons
- C5/6: similar issue as above
- C4 or C3/C4: mostly C4
- C2/3: this includes perfluoroethers and perfluoroether polymers as well as non-polymers
- Mixed: includes ranges of all kinds (e.g., 1-10, or 2-6 or 8-12)

Granted LVEs: Revocation – additional info.

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- Ex. 5 Deliberative Process (DP)

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